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National Institutes of Health  
Bethesda 14, Maryland

Regulations for the Sale of  
Viruses, Serums, Toxins and Analogous Products  
in the  
District of Columbia and in  
Interstate Traffic

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1909



**Amendment No. 1 to the Regulations for the Sale of Viruses, Serums,  
Toxins, and Analogous Products.**

U. S. Public Health Service.

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TREASURY DEPARTMENT,  
OFFICE OF THE SECRETARY,  
Washington, October 27, 1917.

*To manufacturers of viruses, serums, toxins, etc., and others concerned:*

In accordance with the provisions of section 4 of the act of July 1, 1902, paragraphs 4 and 5 of the "Regulations for the sale of viruses, serums, toxins, and analogous products, approved May 11, 1909," have been amended, and are hereby promulgated:

4. Licenses shall be good until suspended or revoked. The following form of license is prescribed:

"This is to certify that \_\_\_\_\_, of \_\_\_\_\_,  
\_\_\_\_\_, hereby authorized under the provisions of 'An act to regulate the sale  
of viruses, serums, toxins, and analogous products in the District of Columbia,  
to regulate interstate traffic in said articles, and for other purposes,' to engage  
in the manufacture, barter, and sale of the following biological products:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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"This license is valid until suspended or revoked in accordance with the  
above-mentioned act and the regulations thereunder.

-----  
"Secretary of the Treasury."

5. Licenses shall not be reissued without inspection of the establishments and laboratory examination of the products. The inspection and laboratory reports shall be passed upon by the sanitary board and the Surgeon General of the Public Health Service in accordance with the provisions of paragraph 3. Inspections of establishments shall be made at least once a year.

L. S. ROWE,  
*Acting Secretary.*



**Amendment No. 2 to the Regulations for the Sale of Viruses, Serums, Toxins, and Analogous Products.**

**United States Public Health Service.**

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TREASURY DEPARTMENT,  
OFFICE OF THE SECRETARY,  
*Washington, December 28, 1917.*

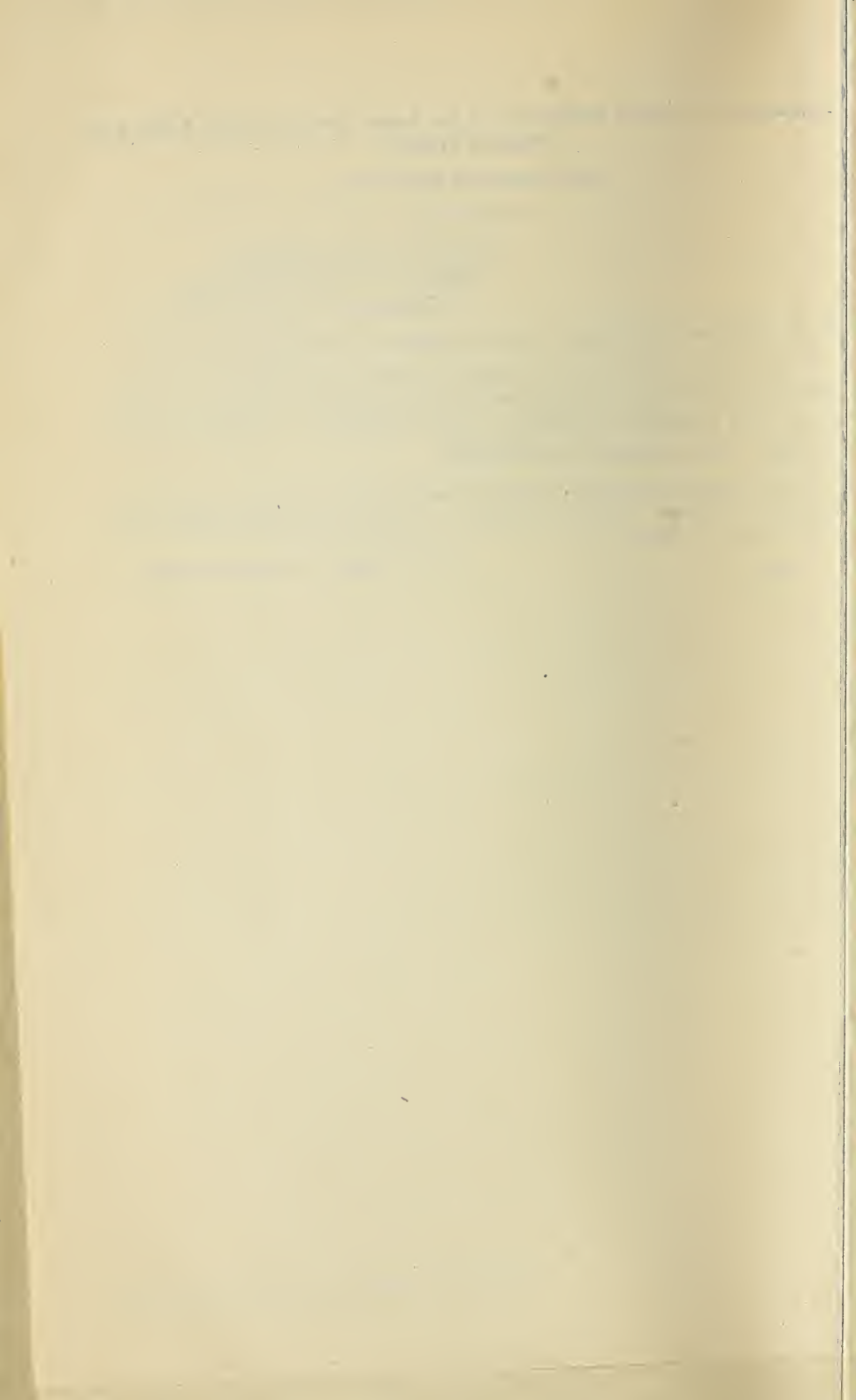
*To manufacturers of viruses, serums, toxins, etc., and others concerned:*

In accordance with the provisions of section 4 of the act of July 1, 1902, paragraph 29 of the "Regulations for the sale of viruses, serums, toxins, and analogous products, approved May 11, 1909," has been amended, and is hereby promulgated:

29. The propagation and sale in interstate traffic of vaccine virus on or with "points" are hereby prohibited. Vaccine virus shall be furnished only in glass capillary tubes or in other glass container.

L. S. ROWE, *Acting Secretary.*

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TREASURY DEPARTMENT  
U. S. Public Health and Marine-Hospital Service

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REGULATIONS  
FOR THE SALE OF  
VIRUSES, SERUMS, TOXINS  
AND ANALOGOUS PRODUCTS  
IN THE DISTRICT OF COLUMBIA  
AND IN INTERSTATE TRAFFIC

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APPROVED MAY 11, 1909



WASHINGTON  
GOVERNMENT PRINTING OFFICE  
1909





REGULATIONS FOR THE SALE OF VIRUSES, SERUMS, TOXINS,  
AND ANALOGOUS PRODUCTS.

TREASURY DEPARTMENT.

*Washington, D. C., May 11, 1909.*

The following regulations have been prepared by the undersigned board of officers in accordance with the provisions of section 4 of an act of Congress approved July 1, 1902, entitled "An act to regulate the sale of viruses, serums, toxins, and analogous products in the District of Columbia, to regulate interstate traffic in said articles, and for other purposes;" they are hereby promulgated and will supersede the regulations issued February 21, 1903, and amendments thereto,

G. H. TORNEY,

*Surgeon-General, U. S. Army.*

P. M. RIXEY,

*Surgeon-General, U. S. Navy.*

WALTER WYMAN,

*Surgeon-General, Public Health and Marine-Hospital Service.*

Approved:

FRANKLIN MACVEAGH,

*Secretary of the Treasury.*



## LICENSES.

### ISSUE OF LICENSES.

1. Licenses shall be issued, suspended, and revoked by the Secretary of the Treasury, upon the recommendation of the Surgeon-General of the Public Health and Marine-Hospital Service.

2. Licenses shall be issued only after inspection of establishments and examination of the products for which license is desired.

3. When an establishment shall have been inspected and the products propagated therein examined in accordance with these regulations, the report of inspection and laboratory examination shall be passed upon by the sanitary board of the Public Health and Marine-Hospital Service. The said board shall present its findings to the Surgeon-General of the Public Health and Marine-Hospital Service who shall review and forward same, together with his recommendations, to the Secretary of the Treasury for action.

4. The following form of license is prescribed:

#### LICENSE.

....., 190  
This is to certify that....., of....., State of....., have complied with the terms of "An act to regulate the sale of viruses, serums, toxins, and analogous products in the District of Columbia, to regulate interstate traffic in said articles, and for other purposes;" that the establishment of the said..... has been duly inspected in accordance with regulations made under the terms of the said act, and that the said..... are hereby authorized to engage in the manufacture, barter, and sale of.....for one year from this date, or until reinspection.

This license is issued in accordance with the regulations prepared under the above-mentioned act, and is subject to suspension or revocation when due cause therefor is shown.

[L. s.]

.....  
*Secretary of the Treasury.*

5. Licenses shall be good for one year from the date of issue (or until reinspection), and will not be reissued without such reinspection and laboratory examination; the report of inspection and laboratory examination to be passed upon by the sanitary board and the Surgeon-General of the Public Health and Marine-Hospital Service, in accordance with the provisions of paragraph 3. Inspections shall be made at least once a year.

## INSPECTION OF ESTABLISHMENTS.

6. The inspection shall be made by an inspector or a board of inspectors detailed by the Secretary of the Treasury upon the recommendation of the Surgeon-General of the Public Health and Marine-Hospital Service.

7. The inspectors shall be commissioned medical officers of the Public Health and Marine-Hospital Service or chiefs of division of the hygienic laboratory of the same service.

8. The visit of the inspectors shall be unannounced.

9. It shall be the duty of the inspectors to call first upon the head of the establishment or member of the firm, stating the object of their visit.

10. The inspectors shall examine all portions of the premises, appliances, stables, barns, warehouses, records, and the methods employed in actual operation.

11. The inspectors are authorized, when they consider it necessary, to interrogate the proprietor, members of the firm, and employees of the establishment under oath.

12. The inspectors shall investigate fully the methods of preparation, storing, dispensing, and other details in the manufacture and sale of serums, viruses, toxins, and analogous products.

13. The inspectors shall carefully examine into faulty construction or administration of establishments which would tend to impair the potency or purity of their products, and shall, if of sufficient importance, make special report regarding the same.

14. It shall be the duty of the inspectors to purchase in open market or, if they deem it advisable, themselves to obtain in the establishment samples of the products then manufactured, which samples shall be examined by the inspectors for purity and potency or forwarded to the director of the hygienic laboratory for such examination.

15. It shall be the duty of the director of the hygienic laboratory of the Public Health and Marine-Hospital Service to test samples sent him by inspectors for purity and potency, and the result of this examination shall be given to the inspectors, who shall give this report due weight in making their recommendations.

## EXAMINATIONS OF VIRUSES, SERUMS, TOXINS, ETC.

16. The terms "virus, serum, toxin, and analogous products" shall include the following products and such others as may be designated by the Secretary of the Treasury from time to time: Antidiphtheric serum or diphtheria antitoxin, antitetanic serum or tetanus antitoxin, antistreptococcic serum, antistaphylococcic serum, antigenococcic serum, antipneumococcic serum or antipneumonic

serum, antidysenteric serum, antituberculous serum, antipest serum, anticholera serum, streptolytic and pneumolytic serum, antimeningococcic serum, antiplague serum, erysipelas and prodigiosus toxins, tuberculins, emulsion tubercle bacilli, suspension of lactic acid bacilli, antityphoid serum, bacterial vaccines, normal horse serum, and vaccine virus.

17. Viruses, serums, toxins, and analogous products propagated in licensed establishments and offered for sale in the District of Columbia, or in interstate traffic, shall be obtained from time to time in the open market and examined under the direction of the Surgeon-General of the Public Health and Marine-Hospital Service as to purity and potency and as to whether said products are properly labeled, as required by section one of the law.

18. Viruses, serums, toxins, and analogous products propagated in licensed establishments and imported from abroad will be detained by customs officers at ports of entry, pending examination by officers of the Public Health and Marine-Hospital Service as to purity and potency and as to whether said products are properly labeled as required by section 1 of the law.

19. Samples of the same laboratory numbers shall accompany each foreign importation of viruses, serums, toxins, and analogous products, and said samples will be forwarded by collectors of customs to the Surgeon-General of the Public Health and Marine-Hospital Service at Washington for examination.

20. Viruses, serums, toxins, and analogous products imported from foreign countries will be refused entry by collectors of customs unless propagated in an establishment holding an unsuspended and unrevoked license, or intended for examination precedent to obtaining a license.

21. The immunity unit for measuring the strength of diphtheria antitoxin shall be that established and distributed by the Public Health and Marine-Hospital Service.

22. The immunity unit for measuring the strength of tetanus antitoxin shall be ten times the least quantity of antitetanic serum necessary to save the life of a 350-gram guinea pig for ninety-six hours against the official test dose of a standard toxin furnished by the Hygienic Laboratory of the Public Health and Marine-Hospital Service.

23. Manufacturers placing on the market serums concentrated by Gibson's method or by any other method, or mixed serums made by mixing concentrated serum with ordinary antitoxic serum, shall be required to so label them.

24. Preliminary to taking vaccine material from vaccinated animals, said animals should be killed or otherwise rendered insensible to pain.



25. As soon as practicable after taking the vaccine virus, a necropsy shall be made upon each animal, and permanent records kept of each necropsy, in which particular reference shall be made of pathologic changes.

26. All vaccine material from any animal having a communicable disease, other than vaccinia, or suspected of having a communicable disease, shall be destroyed.

27. The practice of renting animals for the purpose of propagating vaccine virus and returning the animals to the market shall be discontinued.

28. Animals used for propagating vaccine virus must be under daily veterinary inspection for not less than seven days immediately before they are vaccinated. Only healthy animals free from communicable disease shall be used for this purpose.

29. The propagation and sale in interstate traffic of old-style dry "lymph" vaccine points shall be discontinued after January 1, 1910.

30. Each and every lot of vaccine virus shall be examined to determine its freedom from pathogenic micro-organisms, and a special examination must be made of each and every lot to determine the absence of tetanus; detailed and permanent records of these examinations shall be kept by the establishment propagating said virus.

31. Containers, grinding and mixing machines, filling apparatus, instruments, etc., that come in contact with vaccine material during the process of manufacture and preparation for the market, shall be sterilized before use by steam under pressure at a temperature of at least 120° C. for not less than thirty minutes, or subjected to dry heat at a temperature of at least 160° C. for not less than one hour. Materials that will not stand this degree of dry heat shall be sterilized by a process known to be capable of destroying tetanus spores.

32. Refuse, wastes, excelsior, packing materials such as hay, straw, cotton, etc., crude materials and goods of miscellaneous origin and unknown history shall not be stored or permitted in or about vaccination stables or where the animals used for propagating vaccine virus are kept.

#### SUSPENSION AND REVOCATION.

33. When faulty methods of preparation, faulty construction, or administration of establishments are observed during inspection, the inspector shall bring the same to the attention of the manufacturer, and shall forward a report of the conditions found, together with his recommendations, to the Surgeon-General.

34. When impurities or lack of potency of products, or improper labeling of same shall be demonstrated by laboratory examination, these facts shall be reported to the Surgeon-General.

35. Should the faulty conditions discovered during inspection or laboratory examination be found upon review by the sanitary board and the Surgeon-General to be of sufficient importance, the Surgeon-General shall recommend to the Secretary of the Treasury that the license of the offending establishment be suspended. If the said faulty conditions are not corrected within sixty days after suspension, he shall recommend that the said license be revoked.

36. The facts of suspension and revocation of licenses, with causes therefor, may be published in a circular to be issued and signed by the Secretary of the Treasury.

AN ACT To regulate the sale of viruses, serums, toxins, and analogous products in the District of Columbia, to regulate interstate traffic in said articles, and for other purposes.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,* That from and after six months after the promulgation of the regulations authorized by section four of this Act no person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange from any State, Territory, or the District of Columbia into any State, Territory, or the District of Columbia, or from any foreign country into the United States, or from the United States into any foreign country, any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention and cure of diseases of man, unless (a) such virus, serum, toxin, antitoxin, or product has been propagated and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary of the Treasury as hereinafter authorized, to propagate and prepare such virus, serum, toxin, antitoxin, or product for sale in the District of Columbia, or for sending, bringing, or carrying from place to place aforesaid; nor (b) unless each package of such virus, serum, toxin, antitoxin, or product is plainly marked with the proper name of the article contained therein, the name, address, and license number of the manufacturer, and the date beyond which the contents can not be expected beyond reasonable doubt to yield their specific results: *Provided*, That the suspension or revocation of any license shall not prevent the sale, barter, or exchange of any virus, serum, toxin, antitoxin, or product aforesaid which has been sold and delivered by the licentiate prior to such suspension or revocation, unless the owner or custodian of such virus, serum, toxin, antitoxin, or product aforesaid has been notified by the Secretary of the Treasury not to sell, barter, or exchange the same.

SEC. 2. That no person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, or product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, or product aforesaid so as to falsify such label or mark.

SEC. 3. That any officer, agent, or employee of the Treasury Department, duly detailed by the Secretary of the Treasury for that purpose, may during all reasonable hours enter and inspect any establishment



for the propagation and preparation of any virus, serum, toxin, antitoxin, or product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State, Territory, or the District of Columbia into any other State or Territory or the District of Columbia, or from the United States into any foreign country, or from any foreign country into the United States.

SEC. 4. That the Surgeon-General of the Army, the Surgeon-General of the Navy, and the supervising Surgeon-General of the Marine-Hospital Service, be, and they are hereby, constituted a board with authority, subject to the approval of the Secretary of the Treasury, to promulgate from time to time such rules as may be necessary in the judgment of said board to govern the issue, suspension, and revocation of licenses for the maintenance of establishments for the propagation and preparation of viruses, serums, toxins, antitoxins, and analogous products, applicable to the prevention and cure of diseases of man, intended for sale in the District of Columbia, or to be sent, carried, or brought for sale from any State, Territory, or the District of Columbia, into any other State, Territory, or the District of Columbia, or from the United States into any foreign country, or from any foreign country into the United States: *Provided*, That all licenses issued for the maintenance of establishments for the propagation and preparation in any foreign country of any virus, serum, toxin, antitoxin, or product aforesaid, for sale, barter, or exchange in the United States, shall be issued upon condition that the licentiates will permit the inspection of the establishments where said articles are propagated and prepared, in accordance with section three of this Act.

SEC. 5. That the Secretary of the Treasury be, and he is hereby, authorized and directed to enforce the provisions of this Act and of such rules and regulations as may be made by authority thereof; to issue, suspend, and revoke licenses for the maintenance of establishments aforesaid, and to detail for the discharge of such duties such officers, agents, and employees of the Treasury Department as may in his judgment be necessary.

SEC. 6. That no person shall interfere with any officer, agent, or employee of the Treasury Department in the performance of any duty imposed upon him by this Act or by regulations made by authority thereof.

SEC. 7. That any person who shall violate, or aid or abet in violating, any of the provisions of this Act shall be punished by a fine not exceeding five hundred dollars or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

SEC. 8. That all Acts and parts of Acts inconsistent with the provisions of this Act be, and the same are hereby, repealed.

Approved July 1, 1902.









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